510(k) Summary
Prepared August 22, 2011

SEP 16 2011

1. **Sponsor:** Siemens Medical Solutions, Inc.,
Ultrasound Division
1230 Shorebird Way
Mountain View, California 94043

Contact Person: Shelly Pearce
Telephone: (650) 694-5988
Fax: (650) 694-5580

Submission Date: August 22, 2011

2. **Device Name:** Acuson S2000™ Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System

Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX
Diagnostic Ultrasound Catheter	FR # 870.1200	Product Code OBJ

3. Legally Marketed Predicate Devices

The modified Acuson S2000™Ultrasound System is substantially equivalent to the the company's own Acuson Antares and S2000 Ultrasound Systems.

4. Device Description:

The **S2000™** Ultrasound System is a multi-purpose mobile, software controlled diagnostic ultrasound system with and on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D/4D Imaging on a Flat Panel Display. It is substantially equivalent to our current S2000 product (K093812, K090334, K072786, K081148), and Siemens V7M (K063085), AcuNav 8F and AcuNav 10F (K071234) transducers. These predicates are legally marketed devices.

5. Intended Use

The S2000™ ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, intraoperative neurological, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav Ultrsound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

6. Summary of Technological Characteristics – New Device Compared to Predicate

Feature / Characteristic	Acuson S2000	Acuson Antares K# 063803
Indications for Use:		
▪ Fetal	√	√
▪ Abdominal	√	√
▪ Intraoperative abdominal and vascular	√	√
▪ Intraoperative neurological	--	--
▪ Pediatric	√	√
▪ Small Organ	√	√
▪ Neonatal cephalic	√	√
▪ Adult Cephalic	√	√
▪ Cardiac	√	√
▪ Trans-esophageal	√	√
▪ Transrectal	√	√
▪ Transvaginal	√	√
▪ Peripheral vessel	√	√
▪ Laparoscopic	--	--
▪ Musculo-skeletal (conventional)	√	√
▪ Musculo-skeletal (superficial)	√	√
Center Frequencies Supported:		
▪ 2.0 MHz	√	√
▪ 3.0 MHz	√	√
▪ 3.2 MHz	√	√
▪ 3.3 MHz	√	√

Feature / Characteristic	Acuson S2000	Acuson Antares K# 063803
▪ 4.2 MHz	√	√
▪ 4.4 MHz	√	√
▪ 4.8 MHz	√	--
▪ 5.0 MHz	√	√
▪ 5.2 MHz	√	√
▪ 6.0 MHz	√	√
▪ 6.5 MHz	√	√
▪ 6.9 MHz	√	√
▪ 9.5 MHz	√	√
▪ 10.0 MHz	√	--
Modes:		
▪ B	√	√
▪ Parallel processing in B mode	√	√
▪ M	√	√
▪ PWD (Pulsed Wave Doppler)	√	√
▪ CWD (Continuous Wave Doppler)	√	√
▪ D (Color Doppler)	√	√
▪ Amplitude Doppler	√	√
▪ Combined (BMDC)	√	√
Output Display Standard (Track 3)	√	√
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1
UL 60601-1 Certified	√	√

7. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

Cleared patient contact materials, electrical and mechanical safety are unchanged.

8. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

Since the S2000 uses the same technology and principles as existing devices, clinical data is not required.

9. Summary

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore it is the opinion of Siemens Medical that the S2000 is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Medical Solutions USA, Inc., Ultrasound Group
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

SEP 16 2011

Re: K112596
Trade/Device Name: ACUSON S2000™ Diagnostic System
Regulation Number: 21 CFR 1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: September 6, 2011
Received: September 7, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ACUSON S2000™ Diagnostic System, as described in your premarket notification:

Transducer Model Number

CW2	6C1HD Curved Array	8V3 Phased Array
CW5	4V1 Phased Array	4V1c Phased Array
EC9-4 Curved Array	10V4 Phased Array	6L3
9L4 Linear Array	14L5 SP Linear Array	EV8C4
14L5 Multi-D Array	7CF2 Curved Array	V7M TEE
14L5BV Multi-D Array	9EVF4 Curved Array	AcuNav 8F
4P1 Phased Array	V5Ms Multiplane TEE	AcuNav 10F
6C2 Curved Array	17L5HDS Linear Array	
4C1 Curved Array	18L6 Linear Array	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

1.3 Indications for Use

A. 510(k) Number (if known):

Device Name: S2000™Diagnostic Ultrasound System

Indications for Use:
The S2000™ ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, intraoperative neurological, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav Ultrsound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K112596

Page 1 of _____

1.3 Indications for Use Forms

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **ACUSON S2000 Ultrasound System**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 13, 16
Intraoperative (Note 9)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8,10,15
Trans-esophageal		P	P	P	P	P	P		BMDC	Note 4
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note2,3,4,5,6,7,8,10, 11,14,15
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Other (specify) Neonatal Cardiac		P	P	P	P	P	P		BMDC	Note 3,4,6, 10

N = new indication; P = previously cleared by FDA K063085, K063803, K072786, K081148, K082142, K090334, K093812, K111674

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 9 For example: vascular, abdominal
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 13 STIC
Note 14 eSie™ Touch elasticity imaging / FTI
Note 15 AHP
Note 16 Custom Tissue Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: CW2 Probe for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					P					
Abdominal					P					
Intraoperative (Note 9)					P					
Intraoperative Neurological										
Pediatric					P					
Small Organ (Note 1)					P					
Neonatal Cephalic					P					
Adult Cephalic					P					
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial					P					
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, , K093812, K111674

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 9 For example: vascular, abdominal

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: CW5 Probe for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					P					
Abdominal					P					
Intraoperative (Note 9)					P					
Intraoperative Neurological										
Pediatric					P					
Small Organ (Note 1)					P					
Neonatal Cephalic					P					
Adult Cephalic					P					
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial					P					
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, , K093812, K111674

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 9 For example: vascular, abdominal

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: EC9-4 Curved Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,6,,7,8,10, 11,
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5, 6, 7,8,10, 11,14
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Mary S. Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 9L4 Linear Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,6,7,8,10, 11,14, 16
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Adult Cephalic										
Cardiac		P	P	P		P	P		BMDC	Note 15
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,6, 7,8,10, 11, 14,15
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,6,7,8,10, 11, 14
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,6,7,8,10, 11, 14
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 15 AHP
Note 16 Custom Tissue Imaging

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112396

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 14L5 Multi-D Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,6, 7,8,10, 11, 14
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:
Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 14L5BV Multi-D Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 081148, K093812, K111674

Additional Comments:
Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 4P1 Phased Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8,10
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 6C2 Curved Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 4C1 Curved Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		P	P	P	P	P	P		BMDC	Note2,3,4,5,6,7,8, 10, 11, 14, 16
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ		P	P	P	P	P	P		BMDC	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 6C1HD Curved Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Y	Y	Y	Y	Y	Y		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		Y	Y	Y	Y	Y	Y		BMDC	Note2,3,4,5,6,7,8, 10, 11, 14, 16
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ		Y	Y	Y	Y	Y	Y		BMDC	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		YN	Y	Y	Y	Y	Y		BMDC	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Y	Y	Y	Y	Y	Y		BMDC	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 111674

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 4V1 Phased Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 14, 16
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 10V4 Phased Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	Note 3,4
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 14L5 SP Linear Array Transducer for use with ACUSON S2000
Indications For Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 9)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P		P	P		BMDC	Note 15
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note2,3,4,5,6 ,7,8,10, 11,14,15
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 9 For example: vascular, abdominal
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 15 AHP
Note 16 Custom Tissue Imaging

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 7CF2 Curved array mechanical 3D transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,13
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 13 STIC

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 9EVF4 Curved Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8, 10,11, 13
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8, 10,11
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8, 10,11
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812, k111674

Additional Comments:
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 13 STIC

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: V5Ms Multiplane TEE Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal		P	P	P	P	P	P		BMDC	Note 4
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:
Note 4 Tissue Equalization Technology

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 17L5HDS Linear Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786, K082142, K090334 , K093812, K111674

Additional Comments:
Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI

Mary S Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 13L6 HD Linear Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P		P	P		BMDC	Note 15
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14,15
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Other (specify)										

N = new indication; P = previously cleared by FDA K081148, K082142, K090334, K093812, K111674

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 15 AHP
Note 16 Custom Tissue Imaging

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 8V3 Phased Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	Note 3,4,6
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Neonatal Cardiac		P	P	P	P	P	P		BMDC	Note 3,4,6

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 4V1c Phased Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 3 10
Abdominal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Intraoperative Abdominal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Intraoperative Neurological		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Pediatric		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Small Organ										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Cardiac		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10 15
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10 15
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Neonatal Cardiac		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10

N = new indication; P = previously cleared by FDA K#'s 052410, 051139, 041319, 032114, 022567, 063085, K090334, K093812, K111674

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 15 AHP

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 6L3 Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10, 11
Abdominal										
Intraoperative Abdominal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10, 11
Intraoperative Neurological		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10, 11
Pediatric										
Small Organ		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10, 1
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10 15
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10, 11 15
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10, 11
Musculo-skeletal Superficial		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10, 11
Other (specify)										

N = new indication; P = previously cleared by FDA K#'s 052410, 051139, 041319, 032114, 022567, 002807, 973767, 063085, K090334, K093812, K111674

Additional Comments:
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 15 AHP

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: EV3C4 Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Abdominal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 6 7 8 10
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K#'s 052410, 051139, 041319, 032114, 022567, 002807, 973767, 063085, K090334, K093812, K111674

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: V7M TEE Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal											
Abdominal		P	P	P	P	P	P		P*	P	Note 4
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*	P	Note 4
Small Organ (specify)**											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*	P	Note 4
Trans-esophageal		P	P	P	P	P	P		P*	P	Note 4
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal (Conventional)											
Musculo-skeletal (Superficial)											
Other (specify)											

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, and #K022567, K093812, K111674

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,

B+M+POWER DOPPLER, B+PWD+POWER DOPPLER, B+CWD+POWER DOPPLER, B+CLARIFY VE

Note 2 Ensemble tissue harmonic imaging
Note 4 Tissue Equalization Technology
Note 10 Clarify VE vascular enhancement technology

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: AcuNav 8F Ultrasound Catheter for use with ACUSON S2000

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

	Mode of Operation									
Clinical Application	**A**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Color Velocity Imaging**	**Combined (Specify)**	**Other: Harmonic Imaging**
Ophtalmic										
Fetal										
Abdominal										
Intraoperative (Vascular)										
Intraoperative (Neurological)										
Pediatric		P	P	P	P	P	P		P*	
Small Organ (Specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal		P	P	P	P	P	P		P*	
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Intra-Cardiac)		P	P	P	P	P	P		P*	

P=Previously cleared by the FDA K992631, K033650, K042593, K071234, K093812, K111674

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,

B+M+POWER DOPPLER, B+PWD+POWER DOPPLER, B+CWD+POWER DOPPLER

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: AcuNav 10F Ultrasound Catheter for use with ACUSON S2000

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

	Mode of Operation									
Clinical Application	**A**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Color Velocity Imaging**	**Combined (Specify)**	**Other: Harmonic Imaging**
Ophtalmic										
Fetal										
Abdominal										
Intraoperative (Vascular)										
Intraoperative (Neurological)										
Pediatric		P	P	P	P	P	P		P*	
Small Organ (Specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal		P	P	P	P	P	P		P*	
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Intra-Cardiac)		P	P	P	P	P	P		P*	

P=Previously cleared by the FDA K992631, K033650, K042593, K071234, K093812, K111674

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,

B+M+POWER DOPPLER, B+PWD+POWER DOPPLER, B+CWD+POWER DOPPLER

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112596